**Transhepatic Solution**

Successful transseptal access has been achieved by transhepatic approach. Optimized transseptal approach may be required in:

- **Mitral Valve Repair**
  - Successful transcatheter mitral valve repair has been performed through transseptal access via hepatic venous approach, which provides a direct trajectory to the mitral annulus.

- **Ventricular Tachycardia (VT) Ablation**
  - Successful ablation for atrioventricular nodal reentry tachycardia has been performed in the left ventricle via hepatic venous approach.

- **Impaired Inferior Vena Cava (IVC)**
  - Pulmonary Vein Isolation (PVI)
  - Left Atrial Appendage Occlusion (LAAO)
  - Successful transcatheter therapies such as PVI (cryoablation and RF ablation) and LAAO have been performed through transseptal access via hepatic venous approach in patients with impaired IVC.

**Jugular/Subclavian Solution**

Successful jugular/subclavian venous access cases completed globally using the SupraCross RF Solution. Optimized transseptal approach may be required in:

- **Mitral Valve Repair**
  - Successful transcatheter mitral valve repair has been performed through transseptal access via jugular venous approach, which provides a direct trajectory to the mitral annulus.

- **Ventricular Tachycardia (VT) Ablation**
  - Successful ablation for VT has been performed in the left ventricle via jugular venous approach.

- **Impaired Inferior Vena Cava (IVC)**
  - Pulmonary Vein Isolation (PVI)
  - Left Atrial Appendage Occlusion (LAAO)
  - Successful transcatheter therapies such as PVI (cryoablation and RF ablation) and LAAO have been performed through transseptal access via jugular venous approach in patients with impaired IVC.

**SupraCross™ RF Solutions Include RF Wire and Sheath:**

**A 3-in-1 RF Wire**

- **RF Puncture Technology**
  - Reliably cross normal fibrotic, and aneurysmal septum using a short, focused RF energy pulse.

- **Instantly Secure Access**
  - Flexible spiral tip helps to maintain left atrial access.

- **Sturdy Exchange Rail**
  - 0.035” rail to facilitate sheath exchange with ease.

**B Precision Steerable Sheath**

- **Flexible Dilator**
  - A fully steerable sheath with flexible dilator to facilitate navigating complex anatomy and precise positioning on the fossa.

**TruGlide™ Handling**

- Responsive, smooth, high-precision steering to confidently position your curve.

*Studies used MVE Transseptal Needle, which employs the same RF puncture technology as the SupraCross™ RF Wire.*
SupraCross™ RF Solutions

SPECIFICATIONS

SupraCross™ Steerable Sheath

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<tr>
<th>Product Number</th>
<th>Sheath</th>
<th>Wire</th>
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<tbody>
<tr>
<td>SCAK0001</td>
<td>SupraCross™ Sheath (S)</td>
<td>SupraCross™ RF Wire</td>
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<tr>
<td>SCAK0002</td>
<td>SupraCross™ Sheath (M)</td>
<td>SupraCross™ RF Wire</td>
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<tr>
<td>SCAK0003</td>
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*All SupraCross™ Solutions also include: 0.035” mechanical guidewire. Single-use connector cable, compatible with RFP-100A Generators*

ORDERING INFORMATION

SupraCross™ RF Wire

CAUTION: Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only. Prior to use, please see the complete “Instructions for Use” for more information on Indications, Contraindications, Warnings, Precautions, Adverse Events, and Operator Instructions.

CONTRAINDICATIONS: The SupraCross™ RF Wire is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other RF Generator or any other device.

WARNINGS: 
- The SupraCross™ RF Wire and the Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse the device. Failure to use the device as intended may result in harm to the patient.
- The SupraCross™ RF Wire is designed to be used with the SupraCross™ RF Generator and is not recommended for use with other RF Generators or devices.

PRECAUTIONS: 
- To prevent the risk of infection, ensure that all materials are present in the room during RF power application.
- Do not use the SupraCross™ RF Wire or the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the SupraCross™ RF Wire and the Connector Cable.

ADVERSE EVENTS: Adverse events that may occur while creating an atrial septal defect include: 
- Tamponeade 
- Septal perforation 
- Hypotension 
- Thromboembolic episodes 
- Vessel perforation 
- Atrial fibrillation 
- Myocardial infarction 
- Vessel spasm 
- Sustained arrhythmias 
- Atrial flutter 
- Hemorrhage 
- Vascular thrombosis 
- Perforation of the myocardium 
- Hematoma 
- Atrial reaction to contrast medium 
- Ventricular Tachycardia 
- Pain and Tenderness 
- Artifex erosus foliosus 
- Percutaneous orifice 
- Tachycardia 
- Vascular Trauma 
- Additional Surgical Procedure 
- Wire entrapment 
- Foreign body/wire fracture

SupraCross™ Steerable Sheath

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CONTRAINDICATIONS: The SupraCross™ Steerable Sheath is not recommended for use with any conditions that do not require the creation of an atrial septal defect. The Connector Cable is not recommended for use with any other RF Generator or any other device.

WARNINGS: 
- Laboratory staff and patients can undergo significant x-ray exposure during RF puncture procedures due to the continuous usage of fluoroscopic imaging. This exposure can result in acute radiation injury as well as increased risk for somatic and genetic effects. Therefore, adequate measures must be taken to minimize this exposure.
- The SupraCross™ RF Wire and the Connector Cable are intended for single patient use only. Do not attempt to sterilize and reuse the device. Failure to use the device as intended may result in harm to the patient.

PRECAUTIONS: 
- To prevent the risk of infection, ensure that all materials are present in the room during RF power application.
- Do not use the SupraCross™ Steerable Sheath with the Connector Cable. Excessive bending or kinking of the wire shaft, distal curve of the wire and/or the Connector Cable may damage the integrity of the device components and may cause patient injury. Care must be taken when handling the SupraCross™ RF Wire and the Connector Cable.

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*Baylis Medical Company Radiofrequency Puncture Generator RFP-100A. Baylis Medical Company is a wholly owned subsidiary of Boston Scientific Corporation.

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**Horvath et al. JACC: Cardiovascular Electrophysiology. 2020.*

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